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09/656,084	09/06/2000	Barry N. Kreiswirth	19124.0002	8869

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,084	KREISWIRTH ET AL.	
	Examiner	Art Unit	
	Cheyne D. Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 14, 2004 and January 03, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,10-14,16,17,21-36,38 and 42-44* is/are pending in the application.

4a) Of the above claim(s) *42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,8,10-14,16,17,21-36,38 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-5,7,8,10-14,16,17,21-36,38 and 42-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed October 14, 2004, and January 03, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's interview summary has been accepted.

3. Claims 1, 3-5, 7, 8, 10-14, 16, 17, 21-36, 38, and 44 are examined on the merits. It is noted that claim 38 has been inadvertently omitted from the statement indicating claims under examination in the previous Office Action. Claim 38 has been previously considered as indicated by the prior art rejection in paragraph 42 of the previous Office Action, mailed April 14, 2004. Therefore, the inclusion of claim 38 in the statement above does not raise any new grounds of rejections. It is merely to clarify the record for the inadvertently omission of claim 38 in the main rejection statement.

4. It is noted that the 35 U.S.C. 112, First Paragraph, new matter rejection has been withdrawn because Applicant's pointed to support, filed October 14, 2004, has been found to be persuasive because page 24, lines 17-18, and pages 31-35 provide disclosure of "the relatedness of the bacterial isolate to other isolates" and the comparing of two sequences.

CLAIM REJECTIONS - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3-5, 7, 12-14, 16, 17, 21, 25-34, 36, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (US 5,619,991A) taken with Hoe et al. (1999) in combination with van Belkum et al. (1997).

8. This rejection is maintained with respect to claims 1, 3-5, 7, 12-14, 16, 17, 21, 25-34, 36, and 44, as recited in the previous office action mailed April 14, 2004.

RESPONSE TO ARGUMENT

9. On page 17 of the Response, filed January 03, 2005, Applicant argues that the method of Hoe et al. have spacers between repeat regions, whereas the VNTR sequences of van Belkum et al. do not contain spacers between repeat regions. Therefore, "one skilled in the art would not have been motivated to combine the methods of Hoe et al. with the VNTR sequences of van Belkum et al." Applicant's argument is not persuasive because said argument is specifically directed to the motivation combine the references of Hoe et al. and van Belkum et al. While, Sloane has been cited in the previous Office Action to describe improvements in the method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak), which provides the motivation to combine the teaching from all three references to render the claimed invention obvious over the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak) as directed to sequencing medical data of Sloane, Hoe et al., and van Belkum et al.

10. It is noted that Hoe et al. describes the "M. tuberculosis chromosome that contains up to approximately 40 copies of a 36-bp DR sequence interspersed with unique spacer regions 35 bp to 41 bp in length" (page 259, column 1, lines 20-25). Table 2 of van Belkum et al., pointed to by applicant, does contain interspersed unique spacer regions. For example, van Belkum et al. describes Table 2 comprising potential VNTR sequences in the genome of H. influenzae Rd. Within said genome, Hi 2-1 has the AT repeat appearing in position 9612-9622, and Hi 2-2 has the GC repeat appearing in position 514282-514292. The distance

between 9622 of Hi 2-1 and 514282 of Hi 2-1 has been reasonably construed as a spacer region. The data in the pointed to Table 2 contains VNTR sequences comprising interspersed unique spacer regions within the entire genome. Therefore, one of ordinary skill in the art would not have been motivated by Sloane to combine the methods of Hoe et al. with the VNTR sequences of van Belkum et al. as discussed below.

11. On page 19, Applicant argues that the claimed invention is directed to transferring information about the disease pathogen isolates taken from a patient, an inanimate object, or location, not information about the patient himself as described by Sloane. Applicant's argument is not persuasive. It is noted that only claims 11, 12, 22-27, 32, and 44 which recite the limitation of transmission or sending which could reasonably be construed as the argue limitation of "transfers information about the disease pathogen isolates." Sloane describes the electronic messaging of test results (such as a blood test, sputum analysis or throat culture, etc.) as a form of electronic communications among medical diagnostic centers, laboratory, doctors, and patients (column 1, line 63, to column 2, line 9). Therefore, the citation of Sloane is consistent with the argued limitation in claims 11, 12, 22-27, 32, and 44.

12. Further, Applicant argues that Sloane is directed to diagnosing and treating patients, while the presently-claimed invention seeks to prevent and/or control the spread of disease-causing bacteria and prevent outbreaks related to that spread. Applicant's argument is not persuasive because diagnosing and treating patients is the simplest form of prevent and/or control the spread of disease-causing bacteria and prevent outbreaks related to that spread.

Further, Sloane discloses improvements in the method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak) (Abstract etc. and column 1, line 39 to column 2, line 12).

13. Specific to the argument "Nowhere in the description does Sloane teach or suggest that pathogenic sequence data might be epidemiological data or that such data might even be collected", Sloane describes the electronic messaging of test results (such as a blood test, sputum analysis or throat culture, etc.) as a form of electronic communications among medical diagnostic centers, laboratory, doctors, and patients (column 1, line 63, to column 2, line 9). It has been noted that Sloane does not disclose the limitation of tracking spread of infectious bacteria by sequencing a first region comprising the VNTR sequences. The limitations directed to tracking spread of infectious bacteria by sequencing a first region comprising the VNTR sequences are disclosed by Hoe et al. and van Belkum et al. as discussed below.

14. On page 20, last two lines, Applicant asserts "at the time of the invention, sequencing of pathogenic bacteria would not have been a conventional medical test." Applicant's unsubstantiated assertion is not persuasive. Applicant is invited to provide evidentiary support for said assertion, which is against what is well known in the art for the use of sequencing technology in the area of biomedical research at the time of the instant invention.

15. On page 21, Applicant argues that Sloane does not teach or suggest a system that provides warnings regarding epidemiological events. Applicant's argument is not persuasive. Sloane describes a plurality of processes continuously monitors the entire database of patient transaction records looking for the known signatures of particular respective diseases of epidemiological interest, e.g., influenza, tuberculosis, bronchitis,... and other filoviruses. By being able to identify the geographical and sociological distribution of such diseases, CDC is in a better position to carry out its charter of reporting and/or suggesting treatment modalities for such diseases (column 8, lines 1-18). The citation above is consistent with the limitation of "a warning based on the tracking of the spread of the bacteria" which is the purpose of the CDC.

16. Applicant argues that "the Sloane database would not track the current location of the patient or the current location of the pathogen." Applicant's argument is not persuasive because the argued limitation of "current location" is not present in the claims. As to the limitation of "physical locations" in claim 1, lines 18, the citation of the epidemiological database and physical location from Sloane as discussed below is consistent with the required limitation.

17. It has been noted that Sloane does not disclose the limitation of tracking spread of infectious bacteria by sequencing a first region comprising the VNTR sequences. The limitations directed to tracking spread of infectious bacteria by sequencing a first region

comprising the VNTR sequences are described by Hoe et al. in combination with van Belkum et al. as discussed below.

18. On page 22, Applicant argues that the claimed system uses a method of sequencing, and comparing the nucleotide sequence of, distinct "cassettes" or "repeat sequences" present in the variable number and arrangement within VNTR regions of the pathogenic genome. Applicant's argument is not persuasive because the argued limitations as cited above are not present in the claims. It is noted that claim 1 recites the "sequencing a first region..., the first region consisting essentially of a variable number of tandem repeats (VNTRs) region." Further, the claims do not recite the argued limitation of "actual sequence of nucleotides within these cassettes" as argued by Applicant to be absent from the prior art.

19. Applicant argues that van Belkum et al. does not use the sequence of the repeat cassettes to compare pathogens. Applicant's argument is not persuasive because the limitation of "use the sequence of the repeat cassettes to compare pathogens" is not present in the instant claims.

20. On pages 22-23, Applicant argues that van Belkum et al. fails to disclose sequencing of isolates. Applicant's argument is not persuasive because van Belkum et al. describes the whole genome sequence as determined for H. influenzae (GenBank accession number L42023) was screen with a newly developed algorithm. It is noted that van Belkum et al. does not specifically describe the act of sequencing the H. influenzae isolate. However, as cited below, Hoe et al. describes the sequencing of the sic gene wherein a region contains

repeat sequences to unambiguously differentiate 30 M1 isolates (plurality of bacterium samples) recovered from 28 patients in Texas (Abstract etc.). The sequenced nucleic acid molecules are used to search an emm database maintained in the laboratory (page 255, column 2, Sequence Analysis of emm §, lines 3-10 and Figure 4). Therefore, the disclosure of Sloane, Hoe et al., and van Belkum et al., as a whole, renders the claimed invention obvious over the prior art.

21. On page 24, Applicant argues that van Belkum et al. describes a method directed solely to VNTR region length; therefore, van Belkum et al. cannot be deemed to teach or suggest the analysis of repeat unit nucleotide sequence to different amongst individual bacterial isolates. It is noted van Belkum et al. presents data comprising an electrophoresis gel image (Figures 1 and 2). However, van Belkum et al., in addition to the data pointed to by Applicant, describes the result of the computer-aided searches identifies all 23 potential VNTR loci comprising repeat units ranging from 2 to 6 bases in length and the TA repeat is present in H. influenzae AM20 and AM30 is not present in the genome of the fimbria-deficient Rd strain (page 5018, column 2, Tracking potential VNTRs section).

22. Specific to the argument that van Belkum et al. does not teach or suggest the limitation of sequence within the repeat units is significant, it is noted said limitation is not present in the claims. The instant claims are directed to "variable number of tandem repeats (VNTRs) region" but not the sequence within the repeat units as argued by Applicant.

23. On page 25, Applicant argues that van Belkum et al. does not account for phenotypic differences that may be due to nucleotide changes within repeat units. Applicant's argument is not persuasive because the instant claims do not recite the limitation of "account for phenotypic differences that may be due to nucleotide changes within repeat units."

24. On pages 25-26, Applicant argues that Hoe et al. analyzes the sequences between direct repeat units rather than the repeat units themselves. Applicant further asserts that the claimed invention compares the sequence within repeat cassettes. Applicant's argument is not persuasive because the argued limitations are not present in the instant claims.

25. On page 26, Applicant argues that direct repeat sequences disclosed by Hoe et al. are not VNTRs. The distinction has been as been noted. Further, van Belkum et al. has been cited to describe VNTRs, not Hoe et al. as discussed below. As for Applicant's argument directed to spacer regions, said argument has been addresses above. Further, the claims recite the limitation of "a variable number of tandem repeats region" wherein said limitation does not specifically limit the region to "not include spacer regions." The specification does not specifically define the VNTR region or whether the VNTR region comprises spacer regions or not. Further, Hoe et al. has not been cited for describing VNTRs. van Belkum et al. has been cited for describing VNTRs. Therefore, it is the citation of Sloane, Hoe et al., and Belkum et al., when read as a whole, renders the claimed invention obvious over the prior art.

26. Specific to the claim amendment of "on both a base pair level and a repeat motif level", van Belkum et al. describes the result of the computer-aided searches identifies all 23 potential VNTR loci comprising repeat units ranging from 2 to 6 bases in length and the TA repeat is present in H. influenzae AM20 and AM30 is not present in the genome of the fimbria-deficient Rd strain (page 5018, column 2, Tracking potential VNTRs section).

BASIS FOR REJECTION

27. Sloane describes improvements in the method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak) (Abstract etc. and column 1, line 39 to column 2, line 12). The method of Sloane comprises an epidemiological database computer facility, which collects data from plurality of locations (hospitals and other institutions with medical facilities) and wherein said data comprise various medical, personal and epidemiological data relevant to a patient (column 2, lines 13-24).

28. The network system of Sloane comprises epidemiological database computer facility (centralized database), remote facilities (PC and servers) connected to said network, and exchanges of electronic communications between systems within said network (Figure 1 and column 2, lines 40-59), as in instant claim 32, lines 1-9, and claim 44, line 4.

29. The epidemiological database computer facility correlates epidemiological information of a specific location it receives over time (tracking spread) and returns an electronic message to an e-doc indication the source of disease (column 2, lines 26-39), as in instant claim 1, lines 20-22.

30. The epidemiological database computer facility monitors for the known signatures of particular respective diseases of epidemiological interest, e.g. influenza, tuberculosis etc., identifies the geographical distribution, and reporting/suggesting treatment modalities for such diseases (warning and control) (column 8, lines 2-12). The database record includes patient identification number (ID), name, and address (physical location) (column 6, lines 52-59), as in claim 1, lines 8-10.

31. However, Sloane does not describe the limitation of tracking spread of infectious bacteria by sequencing a first region comprising the VNTR sequences. It is noted that the improvement of an epidemiological database computer facility of Sloane, which collects data from plurality of locations (hospitals and other institutions with medical facilities) and wherein said data comprise various medical, personal and epidemiological data relevant to a patient (column 2, lines 13-24) are directed to any medical data related to an epidemiological event including sequence data.

32. van Belkum et al. describes the importance of VNTR sequences for tracking outbreaks of infectious bacteria such as Staphylococcus aureus wherein the coagulase and protein A genes are clearly polymorphic in their repetitive regions (Van Belkum et al., page 2017, Abstract etc. and column 1, lines 1-29), as in instant claim 1, lines 5-6, claim 7, and claim 32, line 12.

33. van Belkum et al. describes the identification of VNTR sequences as directed to specific patients (Table 1), as in instant claim 1, lines 18-19.

34. Hoe et al. describes a method for tracking pathogenic microbial species in an epidemiologic investigation of putative disease outbreaks (page 254, column 1, lines 1-14) and providing insight to the virulence of the said microbial species (page 261, column 1, lines 51-53 to column 2, lines 1-15), as in instant claims 25-27.

35. The method of Hoe et al. comprises sequencing the sic gene wherein a region contains repeat sequences to unambiguously differentiate 30 M1 isolates (plurality of bacterium samples) recovered from 28 patients in Texas (Abstract etc.). The sequenced nucleic acid molecules are used to search an emm database maintained in the laboratory (page 255, column 2, Sequence Analysis of emm §, lines 3-10 and Figure 4), as in instant claim 1, lines 3-7, claims 28-30, and claim 44, lines 2-3.

36. "For molecular analysis of the GAS causing recent cases, 100 isolates were sent to a laboratory at Baylor College of Medicine (infection control facility) (page 255, column 2, lines 8-11). M1 isolates cultured from patients share a common ancestor (phylogenetically related) and lack readily detectable chromosomal variation (page 254, column 2, lines 2-13 and Figure 1), as in instant claim 1, lines 11-19, claim 32, lines 9-1, and claims 5, 12, and 36.

37. Each allele is characterized by single nucleotide changes resulting in single amino acid substitutions in the resulting M1 protein (page 256, column 1, lines 12-15) and eight new nucleotide substitutions were identified in eight codons, and one codon had a new dinucleotide change (sequence) (page 257, column 1, lines 14-21), as in claims 16 and 17.

38. The M1 isolates includes twenty-three Texas isolates had allele emm1.0 (local and regional) the most common emm1 allele in M1 isolates globally (Figure 1, page 256, column 1, lines 1-20, and Table), as in instant claim 21.

39. It is noted that the laboratory of Hoe et al. is located in Texas, therefore, suggests that the database and the location where the sample is obtained from patients in Texas are in the same location (page 255, column 2, lines 8-11), as in instant claim 4.

40. Further, the database contains sequences from global sources (page 255, lines 28-30) and GenBank, Bethesda, MD, (Figure 1) which is remote from the location where the location of the samples are obtained, as in instant claim 3.

41. The inclusion of a document by Benson et al. is not used as prior art but only to disclose that sequences from GenBank are transmitted via a network from a remote facility with a centralized database (page 4, column 1, Building The Database § and Figure 3) and transmission exchanges occur between research remote infection control facility such as

Baylor College of Medicine (Hoe et al., Figure 1) and NCBI (Benson et al., BLAST sequence similarity searching §), as in instant claim 32, lines 16-20.

42. The submission of sequences from sequencing centers and authors who submit data directly to the collaborating databases (store in a database) (Benson et al., page 4, column 1, Building The Database §, 1-7), as in instant claim 1, lines 8-10, and claim 32, lines 13-15.

43. Further, Benson et al. discloses the GenBank and Entrez are available over the Internet in a client server version or GenBank in a CD-ROM (Benson et al., page 5, column 1, lines 14-32), as in instant claim 33.

44. The sample of Hoe et al. is amplified by PCR and sequenced using oligonucleotide primers (Hoe et al., page 258, column 1, lines 1-7; and page 259, PCR and Sequence Analysis of a Polymorphic Direct Repeat (DR) Chromosomal Region §), as in instant claims 13 and 14.

45. Hoe et al. further describes the "lack of readily available detectable chromosomal variation has limited insights on the molecular origin of new virulent strains" (page 254, column 2, lines 7-13), which suggests slowly mutating nucleic acid region. "Stockbauer et al. Analyzed 165 M1 isolates from diverse localities...and documented a uniquely high level of allelic variation" (page 255, column 1, lines 1-4), which suggests more rapidly mutating nucleic acid region. Therefore, the description above suggests tracking of infection based on slowly and rapidly mutating nucleic acid region as in instant claim 31.

46. Hoe et al. describes many sic alleles are confined to local geographic areas, however, several alleles were found among organisms cultured from patients in Mexico and former East Germany (Hoe et al., page 261, column 2, lines 16-23), as in instant claim 34.

47. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvements of Sloane in the method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak) (Abstract etc. and column 1, line 39 to column 2, line 12) to utilized said method with the outbreak tracking method directed to sequencing of Hoe et al. and VNTR medical data of van Belkum et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use method of treating diseases, and identifying and tracking epidemiological events and/or trends (outbreak) as directed to sequencing medical data of Sloane, Hoe et al., and van Belkum et al.

48. Claims 1, 3-5, 7, 8, 10-14, 16, 17, 21-36, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (US 5,619,991A) taken with Hoe et al. (1999) in combination with van Belkum et al. (1997) in view of O'Brien et al (1997) and Paradiso et al. (PN US 6,404 340 B1).

49. This rejection is maintained with respect to claims 1, 3-5, 7, 8, 10-14, 16, 17, 21-36, 38, and 44, as recited in the previous office action mailed April 14, 2004.

50. It is noted that claim 38 has been inadvertently omitted from the statement indicating claims being rejected in the previous Office Action. Claim 38 has been previously rejected as indicated prior art rejection in paragraph 42 of the previous Office Action, mailed April 14, 2004. Therefore, the inclusion of claim 38 in the main rejection statement above does not raise any new grounds of rejections. It is merely to clarify the record for the inadvertently omission of claim 38 in the main rejection statement.

RESPONSE TO ARGUMENT

51. Applicant's arguments as directed to Sloane, van Belkum et al., and Hoe et al. have been fully considered and responded to above.

52. Specific to the argument, on page 28, directed to claim 16, Hoe et al. describes each allele is characterized by single nucleotide changes resulting in single amino acid substitutions in the resulting M1 protein (page 256, column 1, lines 12-15) and eight new nucleotide substitutions were identified in eight codons, and one codon had a new dinucleotide change (sequence) (page 257, column 1, lines 14-21), as in instant claim 16.

BASIS FOR REJECTION

53. Hoe et al. describes the limitations of claims 1, 3-5, 7, 12-14, 16, 17, 21, 25-34, 36, and 44 as described above.

54. However, Hoe et al. does not describe the limitations of claims 8, 10, 11, 22-24, 35, and 38.

55. O'Brien et al. describes a method of comparing "genetic relatedness among Mycobacterium tuberculosis isolates recovered from patients with active disease" (Page 387, Column 2, Lines 2-5). Due to the tracking of patients' medical records by Bellevue Hospital and the Department of Health in New York City, patients found not adhering to therapy were quarantined (page 389 to 390, Case Report §). This displays tracking a patient's physical location as well as the sharing of patient information as recited in instant claims 11 and 22. Further, O'Brien et al. discloses a linked database of fingerprints from isolates in patients from New York City (page 391, column 1, 38-40), as in instant claim 23.

56. Patient is identified and patient sample analyzed prior confinement in the health care facility (page 389 to 390, Case Report §) as recited in instant claims 8, 35, and 38.

57. The "clinical and demographic features of these patients" (Page 390, column 2, 1st paragraph) were reviewed for population risk factors in addition to determining "ongoing transmission of tuberculosis" (Page 390, column 2, lines 1-19) as recited in claim 10.

58. Paradiso et al. discloses a method for sensing and tracking a patient's physical location during a medical treatment for a specific disease (column 2, lines 32-49), as instant claim and 24.

59. It is noted that the improvement of Sloane of an epidemiological database computer facility, which collects data from plurality of locations (hospitals and other institutions with medical facilities) and wherein said data comprise various medical, personal and epidemiological data relevant to a patient (column 2, lines 13-24) are directed to any medical data directed to a patient. Therefore, the improvement of Sloane is directly applicable to method of tracking disease outbreaks of O'Brien and patients of Paradiso et al.

60. One of ordinary skill in the art at the time of the instant invention would have been motivated by the improvements disclosed by Sloane to track outbreaks of diseases by tracking infected patients in the outbreak as taught by O'Brien and Paradiso et al. Therefore, it would have been obvious to one of ordinary skill in the art to perform the method of tracking outbreaks as taught by Sloane, Hoe et al., and van Belkum et al., and by tracking infected patients in said outbreaks as taught by O'Brien and Paradiso et al.

CONCLUSION

61. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

62. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory

period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

63. This application contains claims 42 and 43 drawn to an invention nonelected, filed December 19, 2001. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

64. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

65. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

66. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

67. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

68. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly

3/15/05

Ardin H. Marschel 3/16/05